



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,263	07/27/2001	Jing Wu	002010-593	7971

21839 7590 08/04/2003

BURNS DOANE SWECKER & MATHIS L L P  
POST OFFICE BOX 1404  
ALEXANDRIA, VA 22313-1404

EXAMINER

KIFLE, BRUCK

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/915,263

Applicant(s)  
Wu et al.

Examiner  
Bruck Kifle, Ph.D.

Art Unit  
1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 6, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 118-120 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 118-120 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Art Unit: 1624

Prosecution in this case has been reopened after an appeals conference in the work group. The examiner has been given a "reasonable" amount of time to expand the search to perform a "reasonable search". Thus, the finality of the rejection of the last Office action is withdrawn.

Applicant's amendments and remarks filed 6/6/03 have been entered. Claims 118-120 are now pending in this application.

***Claim Rejections - 35 USC § 112***

Claims 118-120 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not adequately enabling for the scope of the compounds embraced by the claims.

All of the compounds made are drawn to a narrow group which does NOT give a reasonable assurance that all, or substantially all of them, are useful. The claims are not drawn in terms of a recognized genus but are directed to a more or less artificial selection of compounds.

There is no reason why a claim drawn in this way should not be limited to those compounds which are shown to be both new and useful. An Applicant is not entitled to a claim for the use of a large group of compounds merely on the basis of a showing that a selected few are useful and a general suggestion of a similar utility in the others.

Also, see *In re Surrey* 151 USPQ 724, regarding sufficiency of a disclosure for a Markush group, and MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive

Art Unit: 1624

arts such as the instant pharmaceutical arts. Note in Surrey, in which testing done on a group of homogeneous compounds having the same core was deemed NOT sufficient to support claims to various hetero groups of a much narrower range than is being claimed herein and located at only one position in the formula. The instant scope is enormous, in the billions of compounds, and therefore one compound within its scope is not remotely representative of such a scope. See MPEP 2164.03.

### *Provisos*

There are provisos in the claims that exclude compounds embraced by the claims. If these provisos are present to avoid prior art, applicants are urgently requested to point out these references to the examiner because of their importance in the examination of the claims. Applicants have not respond to this query. For example, should the compound excluded by proviso in AAA be present in the prior art, the use of this compound would render claim 118 obvious because the claim embraces a compound wherein (all else being the same) R<sup>1</sup> is 2,5-difluorophenyl (or 4,5-difluorophenyl) or a compound wherein (again all else being the same) R<sup>2</sup> is ethyl. These compounds are embraced by the instant claim and represent a ring position isomer and a homologue, respectively, of the excluded compound. Should the compound AAA be present in the prior art, claim 118 would be rejected under 35 USC 103 because compounds that differ only by the presence of an extra methyl group are homologues which are of such close structural similarity that the disclosure of a compound renders prima facie obvious its homologue. The homologue is expected to be prepareable by the same method and to have the

Art Unit: 1624

same properties. This expectation is then deemed the motivation for preparing homologues.

Homologues are obvious even in the absence of a specific teaching to methylate, In re Wood 199 USPQ 137; In re Hoke 195 USPQ 148; In re Lohr 137 USPQ 548; In re Magerlein 202 USPQ 473; In re Wiechert 152 USPQ 249; Ex parte Henkel 130 USPQ 474; In re Fauque 121 USPQ 425; In re Druey 138 USPQ 39. In all of these cases, the close structural similarity of two compounds differing by only one (or two) methyl groups sufficed; no specific teaching to methylate was present or required. None of these cases has been overruled and indeed the examiner is unaware of any post Lohr case in which motivation is required to put a methyl group on an old compound.

Alternatively, position isomers are well established as being prima facie structurally obvious. See: Ex parte Engelhardt, 208 USPQ 343, 349; In re Mehta, 146 USPQ 284; In re Surrey, 138 USPQ 67; Ex parte Ulliot 103 USPQ 185; Ex parte Naito 168 USPQ 437, 439; In re Norris 84 USPQ 459; Ex parte Allais 152 USPQ 66; Ex parte Henkel 130 USPQ 474; Ex parte Biel 124 USPQ 109; In re Crownse 150 USPQ 554; In re Fouche 169 USPQ 431; Ex parte Ruddy 121 USPQ 427; In re Wiechert 152 USPQ 249.

For example "Position Isomerism has been used as a tool to obtain new and useful drugs" (Engelhardt), and Position isomerism is a fact of close structural similarity" (Mehta, emphasis in the original).


Art Unit: 1624

The search revealed that the elected compound is disclosed in several of Applicants pending applications. See for example WO 99/67221 and WO 98/28268. Also, WO 2001/034571 overlaps generically. Applicants are required to maintain a clear line of demarcation between the corresponding US applications and the instant application. See MPEP § 822. Applicants need to point out what the differences in scopes are.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

July 29, 2003

  
**Bruck Kifle**  
**Primary Examiner**  
**Art Unit 1624**